OCT 2 4 2001

K011056

510(k) Premarket Notification: Arrow-Trerotola™ Percutaneous Thrombolytic Device

SECTION 2. 510(K) SUMMARY

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ARROW INTERNATIONAL

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Date summary prepared: 04/03/01

Device trade name: Arrow-Trerotola™ Percutaneous Thrombolytic Device (PTD™)

Device common name: Thrombolytic device, thrombolytic catheter and PTD™

Device classification name: Class II at 21 CFR 870.5150, Embolectomy catheter

Legally marketed devices to which the device is substantially equivalent:

K990829 Arrow-Trerotola™ Percutaneous Thrombolytic Device

Description of device

The Arrow-Trerotola™ PTD™ Catheter Assembly consists of two components, an outer cover sheath and an inner flexible torque cable with a self-expanding fragmentation basket attached to its distal end. The PTD™ fragmentation basket is constructed of four wires that are formed into a helical cage with a soft, flexible tip located on its distal end. The PTD™ catheter is designed to be used in conjunction with the Arrow Rotator Drive Unit that spins the basket at approximately 3000rpm. A drive hub on the proximal end of the catheter assembly mates with a drive gear in the Rotator Drive Unit. The cable stop on the catheter assembly secures the PTD™ Catheter to the Rotator Unit during operation.

The PTD™ outer sheath moves relative to the inner torque cable and is used to collapse and expand the fragmentation basket. The catheter is placed inside the clotted fistula with the basket in the closed position. After insertion, the basket is fully deployed inside the fistula to conform to the fistula wall. The basket is then rotated which pulverizes the clot; the clot is aspirated from the graft through an introducer sheath.

The PTD™ catheter is manufactured in two lengths, 65cm and 120cm, with a basket diameter of 9mm. It is also available in an Over-The-Wire (OTW) version, which allows the device to be passed over a guidewire.

Intended use of the device:

The Arrow-Trerotola™ Percutaneous Thrombolytic Device (PTD™) Catheter, in conjunction with the Arrow Rotator Drive Unit, permits mechanical declotting of native arterio-venous fistulae and synthetic dialysis grafts.

Technological characteristics:

The proposed device has the same technological characteristics as the predicate device.

Performance tests:

The expanded indications for use to include native arterio-venous fistulae is based on the clinical data presented in the performance section of the submission.

Conclusions:

The Arrow-Trerotola™ PTD™ is as safe and effective as the legally marketed predicate device for the mechanical declotting of native arterio-venous fistulae.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 24 2001

Mr. Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
Arrow International
2400 Bernsville Road
Reading, PA 19605

Re: K011056
Trade Name: Arrow-Trerotola Percutaneous Thrombolytic Device (PTD)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (two)
Product Code: DXE
Dated: July 27, 2001
Received: July 31, 2001

Dear Mr. Nickel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 12. INDICATIONS FOR USE STATEMENT

510(k) Number K011056

Device Name: Arrow-Trerotola™ Percutaneous Thrombolytic Device (PTD™)

Indications For Use: The Arrow-Trerotola™ Percutaneous Thrombolytic Device (PTD™) Catheter, in conjunction with the Arrow Rotator Drive Unit, permits mechanical declotting of native arterio-venous fistulae and synthetic dialysis grafts.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011056